the activity of other protein(s) essential for the functioning of efp.

15. (Amended) The method of claim 1 wherein efp is isolated from a natural source.

REMARKS

Claims 1-141 are pending in the present application. Claims 9-14 and 19-139 have been canceled without prejudice to their presentation in another application. Claims 6 and 15 have been amended. No new matter has been added. Upon entry of the present amendment, claims 1-8, 15-18, 140 and 141 will be pending.

I. Summary of the Amendments

Claim 6 has been amended to essentially substitute the term "interfering" with "modifying" or "modulate." Support for this amendment is found throughout the specification. No new matter has been added.

Claim 15 has been amended to depend solely from claim 1.

II. The Claims Are Clear And Definite

Claims 1-8, 15-18 and 140-141 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In particular, claim 1, and claims depending therefrom, are purportedly indefinite because the claims do not recite whether modulation is upward or downward. Claim 6 is purportedly indefinite because it is unclear whether "interfering" is negative or positive or to what extent the compound is interfering. The Examiner also contends that the phrase "other protein" of claim 6 is not properly described or named. Claim 7 is purportedly indefinite because the meaning of L16 in the claim is not "spelled out." Finally, claim 15 is purportedly indefinite because it depends from two non-elected claims. Applicants traverse the rejection and respectfully request reconsideration because the claims are clear and definite.

With respect to claim 1, Applicants reiterate that modulation can be either an increase or

decrease. Indeed, Applicants teach at page 10, lines 12-13 of the specification that the term "modulates" means an increase or decrease. In absence of evidence that the term "modulation" is indefinite, Applicants claims are not indefinite simply because they are not limited to an increase or decrease.

In regard to claim 6 and the claim term "interfering," although Applicants believe that the claim is clear and definite as originally drafted, solely to advance prosecution of the present application, Applicants have amended claim 6 to be even more clear and definite and to be consistent with language used in claim 1. The terms "modulate" or "modifies," however, should not necessarily be construed as coterminous with the term "interfering." The amendment to claim 6 renders the indefiniteness rejection moot.

Claim 6 is also purportedly indefinite based on the lack of necessary description accompanying the phrase "other protein." In making this rejection, however, the Examiner fails to read the claim in its entirety. The language of the claim reads "other protein(s) essential for the functioning of efp." Examples of such proteins are set forth in the specification. A particular example is the L16 protein. Accordingly, the Examiner is incorrect that "other protein" is not described.

With respect to claim 7, Applicants point out that the term "L16" is defined in the specification at, for example, page 2, lines 29-30, as the N-terminal fragment of the 50S subunit. There is no requirement that further elaboration is required in the claim itself. Moreover, one of ordinary skill in the art would understand the term "L16" even in the absence of a definition in the specification.

Regarding claim 15, Applicants' amendment making the claim dependent solely on claim 1 renders this rejection moot.

Persons of ordinary skill would have no difficulty in determining whether a particular method meets the criteria recited in the claims. Accordingly, the claims are definite within the meaning of §112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Thus, claims 1-8, 15-18 and 140-141 are clear and definite. Accordingly,

Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

III. The Claimed Invention Is Sufficiently Enabled

Claims 1-8, 15-18, 140 and 141 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The rejection is based, in large part, on purported lack of specific, new, and useful assays in the specification. The Office Action, mistakenly concludes that it would require undue experimentation for one skilled in the art to practice the full scope of the claims. Applicants traverse the rejection and respectfully request reconsideration because one skilled in the art would be able to practice the claimed invention without being required to perform undue experimentation.

As will be recognized, the enablement requirement of §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation). In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

> The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.
>
> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken as in compliance with the enabling requirements of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. (emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974). No such evidence, however, has been provided to support the position taken in the Office Action.

Applicants recognized the critical role efp and related compounds play in the catalytic function of ribosomes and, relatedly, in the synthesis of polypeptides in procaryotic organisms. Accordingly, the present invention is directed, in part, to new and useful methods of screening compounds that modulate efp and efp-associated cell functions. Methods include, for example, *in vitro* cell-based and cell-free-extract assays to determine the affect of the compound on cell function. Compounds affecting such cell functions have the potential to mediate cell viability and, thus, are candidates for use in treating microbial infections in mammals and as disinfectants.

The claims of the present application, drawn to methods of screening compounds that modulate efp, are properly tailored to this invention, as heretofore discussed and are, moreover, amply supported by Applicants' disclosure. Importantly, any of Applicants' underlying assays (Examples 1-5) may be employed to practice the claimed method. One of ordinary skill will recognize that the claims do not depend upon any particular underlying assay employed. To this end, the assay may vary, and may even include, and indeed do include, assays not set forth in the specification. In addition, the assay employed may be modified as the practitioner in the art sees fit. The Office Action's rejection of the claims based on a lack of enabling assays, therefore, are unsupported. Indeed, no amount of undue experimentation is required to practice any of the assays.

The Examiner curiously argues that the specification provides no "specific" or "new" assays to accompany the claimed method. In support, the Examiner points out that while Applicants claim a "new *in vivo* method," the underlying assays are old methods. Applicants fail to see the significance of these arguments. As discussed above, Applicants' methods are novel in that they provide methods of screening compounds that modulate efp. There is no disclosure of such methods as applied to efp in the prior art. Hence, they are "new." Moreover, there is no requirement that Applicants must provide a "specific" underlying screening technique. Again, Applicants' claims are

drawn to screening compounds that modulate efp. Therefore, and as discussed above, the underlying assay may vary or may be modified. Importantly, such discretion allowed by the claims are not outside of the knowledge of those of ordinary skill and are therefore not fatal. Consequently, Applicants need not disclose every possible means of practicing the invention, just representative, useful examples. Lastly, to the extent that any of the method claims are supported by "old methods," the law clearly states that novel methods may encompass aspects of the prior art. In fact, most, if not all inventions incorporate known elements.

The Office Action also erroneously argues that the specification is non-enabling because Applicants do not supply information as to whether the claimed modulation is up or down. To this end, the Office Action points out that the Aoki reference (*J. Biol. Sci.*, **1997**, *272*, 32254-32259) demonstrates elimination of certain genes expressing ribosomal proteins does not effect cell viability. This reference, however, does not teach that elimination of the gene encoding efp has no effect on cell viability. In fact, the Aoki reference unequivocally teaches otherwise (see pages 32254 ("efp gene is essential for cell viability and is required for protein synthesis") and 32259 ("a comparison of the growth and radioactive labeling properties a. . . of the mutant harboring the efp gene . . . suggests that the efp gene is required for protein synthesis in vivo.")). Applicants disclose that efp and efp-associated proteins are indispensable with respect to prokaryotic cell function and, absent evidence to the contrary, this disclosure must be taken as true. Absent such countervailing proof, Applicants need not characterize modulation as upward or downward in the claim itself.

Applicants have provided useful, representative examples in the specification that allow the skilled artisan to use and practice the claimed invention without being required to perform any amont of undue experimentation. The Office Action fails to demonstrate countervailing evidence that such assays are inadequate. Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation in order to make and use the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

IV. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (215) 564-8906 if there are any questions regarding Applicants' claimed invention. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully submitted,

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Date: **April 19, 2001**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 9-14 and 19-139 have been cancelled.

Claims 6 and 15 have been amended as follows:

6. (Amended) The method of claim 1 further comprising step:

(c) determining whether said compound which modulates the activity [interfering with the function] of efp modifies the activity of [is interfering with] other protein(s) essential for the functioning of efp.

15. (Amended) The method of [any one of claims] claim 1 [, 9 and 13] wherein efp is isolated from a natural source.